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APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 60/549,930

FILING DATE: March 05, 2004

By Authority of the
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L. EDELEN
Certifying Officer

13281 U.S.PTO

PTO/SB/16 (08-03)

Approved for use through 07/31/2006. OMB 0651-0032

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. _____

U.S.PTO

60/549930

030504

INVENTOR(S)

| | | |
|--|------------------------|---|
| Given Name (first and middle [if any]) | Family Name or Surname | Residence (City and either State or Foreign Country) |
| DORON ADI | LEVITAS SHECHTMAN | TEL-AVIV, ISRAEL NOFIT, ISRAEL |

Additional inventors are being named on the _____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

AN INCLINATION MEASURING DEVICE

Direct all correspondence to:

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| Address | P.O.B. 2345 | | | |
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| City | BEIT SHEMESH | State | | Zip 99544 |
| Country | ISRAEL | Telephone | 516-620-4572 (US) | Fax 516-620-4572 (US) |

ENCLOSED APPLICATION PARTS (check all that apply)

| | | |
|---|--------------------------|-----------------------|
| <input checked="" type="checkbox"/> Specification Number of Pages 8 | <input type="checkbox"/> | CD(s), Number _____ |
| <input checked="" type="checkbox"/> Drawing(s) Number of Sheets 5 | <input type="checkbox"/> | Other (specify) _____ |
| <input type="checkbox"/> Application Date Sheet. See 37 CFR 1.76 | | |

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- Applicant claims small entity status. See 37 CFR 1.27.
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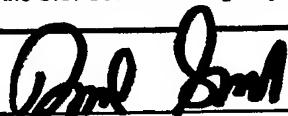
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

 No. Yes, the name of the U.S. Government agency and the Government contract number are: _____

[Page 1 of 2]

Respectfully submitted,



Date March 5, 2004

SIGNATURE _____

REGISTRATION NO. 45,148

TYPED or PRINTED NAME DANIEL J. SWIRSKY

(if appropriate)

TELEPHONE 516-620-4572 (US)

Docket Number: 1301-USP

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13281
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Effective 1010112003. Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 80.00)

Complete if Known

| | |
|----------------------|---------------|
| Application Number | |
| Filing Date | MARCH 5, 2004 |
| First Named Inventor | Doron LEVITAS |
| Examiner Name | |
| Art Unit | |
| Attorney Docket No. | 1301-USP |

METHOD OF PAYMENT (check all that apply)

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FEE CALCULATION

1. BASIC FILING FEE

| Fee Fee Code (\$) | Fee Fee Code (\$) | Fee Description | Fee Paid |
|-------------------|-------------------|------------------------|----------|
| 1001 770 | 2001 385 | Utility filing fee | 80.00 |
| 1002 340 | 2002 170 | Design filing fee | |
| 1003 530 | 2003 265 | Plant filing fee | |
| 1004 770 | 2004 385 | Reissue filing fee | |
| 1005 160 | 2005 80 | Provisional filing fee | |
| SUBTOTAL(1) (\$) | | 80.00 | |

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| Total Claims | -20- = | X | Fee Paid |
|--------------------|--------|---|----------|
| Independent Claims | - 3 - | X | |

| Large Entity Fee Fee Code (\$) | Small Entity Fee Fee Code (\$) | Fee Description |
|--------------------------------|--------------------------------|---|
| 1202 18 | 2202 9 | Claims in excess of 20 |
| 1201 86 | 2201 43 | Independent claims in excess of 3 |
| 1203 290 | 2203 145 | Multiple dependent claim, if not paid |
| 1204 86 | 2204 43 ** | Reissue independent claims over original patent |
| 1205 18 | 2205 9 ** | Reissue claims in excess of 20 and over original patent |
| SUBTOTAL (2) (\$) | | |

**or number previously paid, if greater; For Reissues, see above

| 3. ADDITIONAL FEES | | Fee Description | Fee Paid |
|-----------------------------------|--|--|----------|
| <u>Large Entity</u> | | Small Entity | |
| Fee Fee Code (\$) | | Fee Fee Code (\$) | |
| 1051 130 | | 2051 65 Surcharge -late filing fee or oath | |
| 1052 50 | | 2052 25 Surcharge - late provisional filing fee or cover sheet | |
| 1053 130 | | 1053 130 Non-English specification | |
| 1812 2,520 | | 1812 2,520 For filing a request for ex parte reexamination | |
| 1804 920* | | 1804 920* Requesting publication of SIR prior to Examiner action | |
| 1805 1,840* | | 1805 1,840* Requesting publication of SIR after Examiner action | |
| 1251 110 | | 2251 55 Extension for reply within first month | |
| 1252 420 | | 2252 210 Extension for reply within second month | |
| 1253 950 | | 2253 475 Extension for reply within third month | |
| 1254 1,480 | | 2254 740 Extension for reply within fourth month | |
| 1255 2,010 | | 2255 1,005 Extension for reply within fifth month | |
| 1401 330 | | 2401 165 Notice of Appeal | |
| 1402 330 | | 2402 165 Filing a brief in support of an appeal | |
| 1403 290 | | 2403 145 Request for oral hearing | |
| 1451 1,510 | | 1451 1,510 Petition to institute a public use proceeding | |
| 1452 110 | | 2452 55 Petition to revive - unavoidable | |
| 1453 1,330 | | 2453 665 Petition to revive - unintentional | |
| 1501 1,330 | | 2501 665 Utility issue fee (or reissue) | |
| 1502 480 | | 2502 240 Design issue fee | |
| 1503 640 | | 2503 320 Plant issue fee | |
| 1460 130 | | 1460 130 Petitions to the Commissioner | |
| 1807 50 | | 1807 50 Processing fee under 37 CFR 1.17(q) | |
| 1806 180 | | 1806 180 Submission of Information Disclosure Stmt | |
| 8021 40 | | 8021 40 Recording each patent assignment per property (times number of properties) | |
| 1809 770 | | 2809 385 Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 770 | | 2810 385 For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 770 | | 2801 385 Request for Continued Examination (RCE) | |
| 1802 900 | | 1802 900 Request for expedited examination of a design application | |
| Other fee (specify) | | | |
| *Reduced by Basic Filing Fee Paid | | SUBTOTAL (3) (\$) | |

(Complete if applicable)

| SUBMITTED BY | Name (Print/Type) | DANIEL J. SWIRSKY | Registration No. (Attorney/Agent) | 45,148 | Telephone | 516-620-4572 (US) |
|--------------|-------------------|-------------------|--------------------------------------|--------|-----------|-------------------|
| Signature | | | | | Date | MARCH 5, 2004 |

AN INCLINATION MEASURING DEVICE

FIELD OF THE INVENTION

The present invention relates to an inclination measuring device, and more particularly to an inclination tracking device including means for mapping the degree of inclination and
5 rotation of an object.

BACKGROUND OF THE INVENTION

It is often desirable to measure the degree of inclination of the object. It is especially important in the medical field, for example in measuring the degree of trunk inclination in patients having scoliosis. In order to avoid the over-referral of patients who may have
10 scoliosis, it is common to use a scoliosis screening device (commonly known as a "Scoliometer"), such as that described in US Patent No: 5,181,525, to determine the angle of trunk rotation. The angle of trunk rotation is defined as: "the angle between the horizontal and
• a plane across the posterior trunk at the point or points of maximum deformity."

Scoliosis refers to a lateral spinal curve of a certain degree that affects a large number
15 of people. A contour mapping system and method for mapping the contour of an object such as a person's spine is described in US Patent No: 6,524,260 assigned to the applicants of the present invention. US Patent No: 6,524,260 describes a diagnostic system and method which avoids the risk of radiation exposure and which is capable of providing more detailed
• information about the examined spine, such as the degree of curvature of the spine, or the
20 degree of rotation of any particular vertebra therein. The mapping of the curvature of a person's spine enables the presence and severity of a deformation in the spine, such as scoliosis or Kyphosis to be detected.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding, the invention will now be described, by way of example only, with reference to the accompanying drawings in which like numerals designate like components throughout the application, and in which:

5 Fig. 1 is a schematic illustration of the inclination measuring device, constructed and operative in accordance with an embodiment of the present invention;

Fig. 2 is a side elevational view of a patient, whose angle of trunk rotation is being measured;

Fig. 3 is a view of the vertebrae of a spine;

10 Fig. 4 is a graphical illustration of the results of the measurements of a trunk rotation, using the device of Fig. 1; and

Fig. 5 is a schematic illustration of the inclination measuring device, constructed and operative in accordance with a further embodiment of the present invention.

DESCRIPTION OF THE INVENTION

The applicants have realized that it would be advantageous to be able to automatically or semi-automatically measure the angle of inclination of an object degree of rotation of a deformity of a person's back, for example. The applicants have further realized that it would 5 be advantageous to be able utilize a contour mapping system to map and graphical output the results of the measurement of the angle of inclination. A contour mapping system is described in US Patent Nos: 6,500,131 and 6,524,260, assigned to the applicants of the present invention, the contents of which are incorporated herein.

In one embodiment of the invention, a non-invasive, automatic or semi-automatic 10 system and method to measure the degree of rotation of a deformity of the back found on routine spinal examination is provided.

Reference is now made to Fig. 1, which is a schematic illustration of an inclinometer (or inclination measuring device), generally designated 10, which is constructed and operative 15 in accordance with an embodiment of the present invention. The inclinometer 10 comprises an inclination tracking device 12 suitably attached to a sensor probe 14.

The inclination tracking device 12 comprises a substantially rectangular element 16 having an indentation or semi-circular arch 20 formed in the center of one edge of element 16. The arch is configured to pass over the spinal column. In one embodiment of the invention, the arch 20 may be approximately 3cm in diameter. The inclinometer 10 comprises a pair of 20 tracking devices 22a, 22b attached on either side of the arch 20, along the bottom edge of element 16. The tracking devices 22a, 22b provide stability and allow the inclination tracking device 12 to stay on track and glide over the back. In an exemplary embodiment of the

invention, small wheels may be fitted to the tracking devices 22a, 22b. In an exemplary embodiment of the invention, the inclinometer 10 may be formed from non-warp, lightweight and hygienic material.

The sensor probe 14 may be configured to be removable from the inclinometer 10. In 5 one embodiment of the invention, the sensor probe 14 is configured to be attached to a person's finger.

The spinal curve is sensed in the described preferred embodiments by the sensor probe, which is fitted to a finger, sensing the spinous process of each vertebra.

In an embodiment of the invention, sensor probe 14 may be in communication with a 10 position tracking system 24, which may of an electromagnetic field type, as described in US Patent No: 6,524,260.

The sensor probe 14 is configured to measure the position and inclination of the inclination tracking device 12 as it is moved along an object, such as a spine, for example. Since the position of the sensor probe 14 is fixed in relation to the inclination tracking device 15 12, the inclinometer 10 does not need to be calibrated each time it is used.

The tracked positions may be recorded in an input/output storage device for further processing. In addition, the output of the workstation can be transmitted via a telecommunication device to a remote location, via a telephone line, for viewing, recording, or further processing, for example.

20 The inclinometer 10 may be used for preventive health screening and in the orthopedic field. By using the inclinometer as an accurate automatic or semi-automatic first-level screening of school-aged children for spinal deformities, such as scoliosis and kyphosis, for

example, the school screening system can quickly and efficiently filter out children needing further testing.

Furthermore, in the orthopedic field, the inclinometer 10 may be incorporated into the contour mapping system described in US Patent Nos: 6,500,131 and 6,524, 260 (assigned to 5 common assignees of the present application), to semi-automate the trunk rotation measurements as a part of the standard spine scan procedure.

In the exemplary application of this embodiment, the inclinometer 10 may be used to measure the trunk rotation of a patient, for example, as described hereinbelow.

Measurement of Trunk Rotation

To measure the trunk rotation of a patient, the patient should hold out his arms 10 perpendicular to his body with palms touching while standing. The patient should then bend over as far as possible (see Fig. 2), with the emitter approximately at the level of the naval. The patient's shoulders should be approximately at the hip level (if physically possible).Trunk rotation may be measured by holding the inclinometer 10 with one hand perpendicular to the back with the indented semi-circular arch 20 over the spinous process of C7. The inclinometer 15 10 should then be glided over the spine (following the spine contour as closely as possible) from C7 (see fig. 3) down to S1 (start of the sacrum) The examiner should use his/her free hand to palpate gently down the spine and guide the inclinometer 10 over the spine contour.

The sensor 14 may be configured to take at least one reading per vertebrae and 20 preferably a plurality of readings along the back contour. In an exemplary embodiment, the sensor 14 records 40 readings per second. The system is configured to output quantitative measurements (in degrees) of the maximal trunk rotation measurements in the upper thoracic, mid-thoracic, and lumbar regions. In addition the vertebral level of the trunk rotation

measurements and the direction of the inclination (that is the difference in height between left and right may also be calculated.

Since the inclinometer 10 of the present invention uses a tracking device 12 in communication with a sensor 14, the measurement of a patient's back is not dependent on the 5 patient bending over into an almost horizontal position (the non-limiting example of Fig 2) in order to obtain accurate readings. As will be appreciated by persons skilled in the art, the inclinometer is a digital device and is capable of measuring angular deviation irrespective of the position of object being measured. Thus, accurate results of trunk rotation, for example, may be obtained from a patient in any position, which is a major advantage over prior art 10 devices.

Fig. 4 is an exemplary graphical illustration of the results of the measurement of trunk rotation. As shown, the screen displays the X,Y,Z coordinates of readings 35 to 56 and a graphical display of these readings in Coronal, Sagittal (top right) and Apical (bottom right) views. The display also highlights the maximum inclination and location of the vertebrae in each of the upper thoracic, lower thoracic and lumbar regions. In the example shown, the 15 maximum inclination in the upper thoracic region is 4 degrees on vertebrae T5. In the lower thoracic region the maximum inclination is 4 degrees on vertebrae T7 and in the lumbar region, the maximum inclination is 3 degrees on vertebrae L5. It will be appreciated by persons skilled in the art that computer processing techniques allow for the processing of data 20 and for output in any format, and is not limited by the example given. In a further embodiment of the invention, as shown in Fig. 5, to which reference is now made, the inclination tracking device 12 may be used as a stand-alone device. As will be appreciated by persons skilled in the art, the inclination tracking device 12 and sensor probe 14 may be

adapted to incorporate the storage 102 and computing capabilities 104 within the inclination tracking device 12 itself, which may also be fitted with a display screen 106. The inclination tracking device 12 may also be fitted with a transmitting device 108 for transmitting data to an external source.

5 In a further embodiment of the invention, the inclinometer 10 may be configured to incorporate a gyroscopic device for calculating the angles of inclination instead of a magnetic field generator of Fig. 1. Furthermore, the gyroscopic inclinometer device, which may also be utilized as a stand-alone device, may be adapted to incorporate storage and computing capabilities and be fitted with a display screen.

10 In a further embodiment of the invention, the inclinometer or inclination measuring device may be configured to incorporate special markers. The markers may be used in conjunction with Optical 3D tracking systems (instead of a magnetic field generator of Fig. 1.), such as infra red (IR) or other cameras, to identify and calculate the inclination angles

15 The above examples and description have been provided only for the purpose of illustration, and are not intended to limit the invention in any way. As will be appreciated by the skilled person, the invention can be carried out in a great variety of ways, employing more than one technique from those described above, all without exceeding the scope of the invention.

CLAIMS

1. An inclination measuring device substantially as described hereinabove.
2. An inclination measuring device substantially as illustrated in the drawings.

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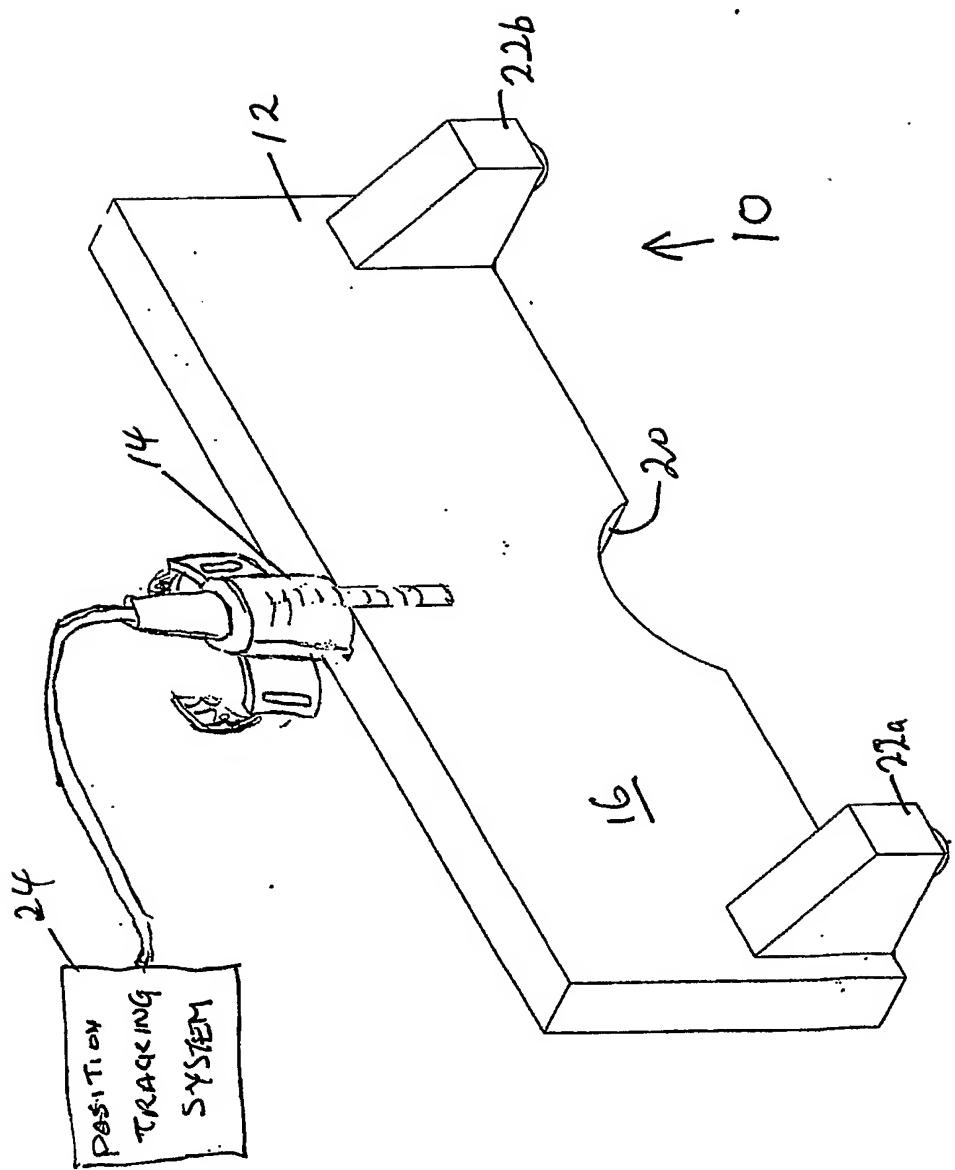


FIG. 1

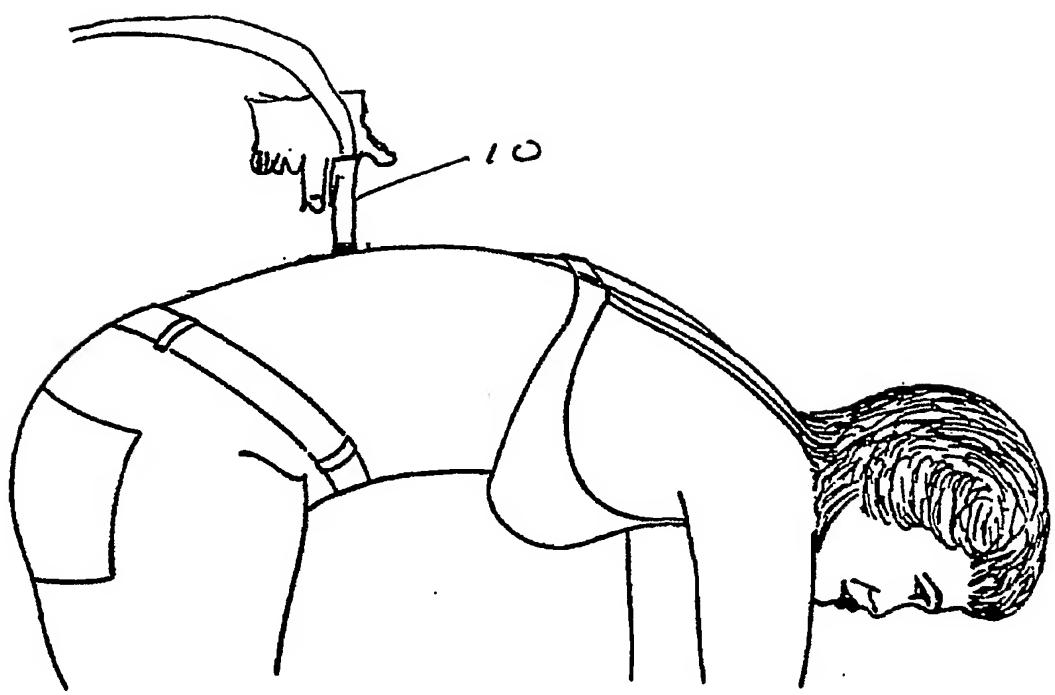


FIG 2

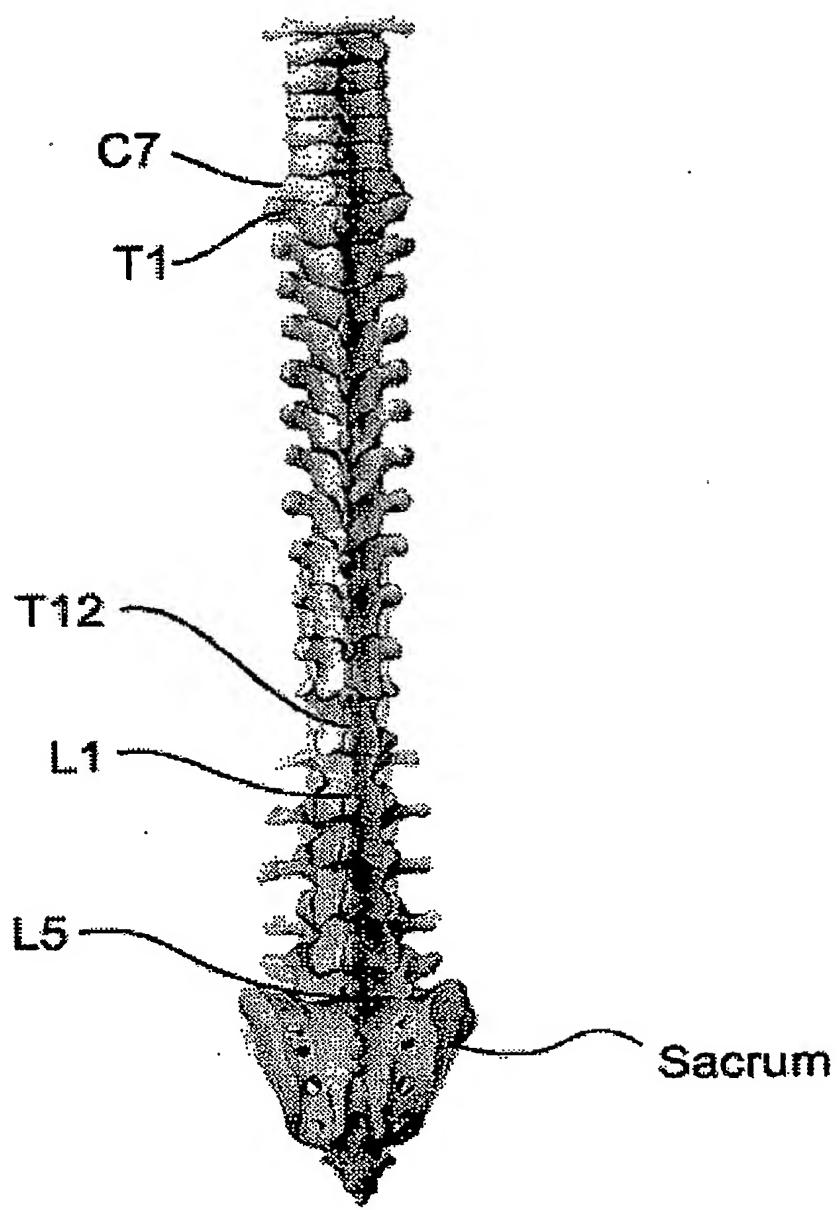


FIG 3

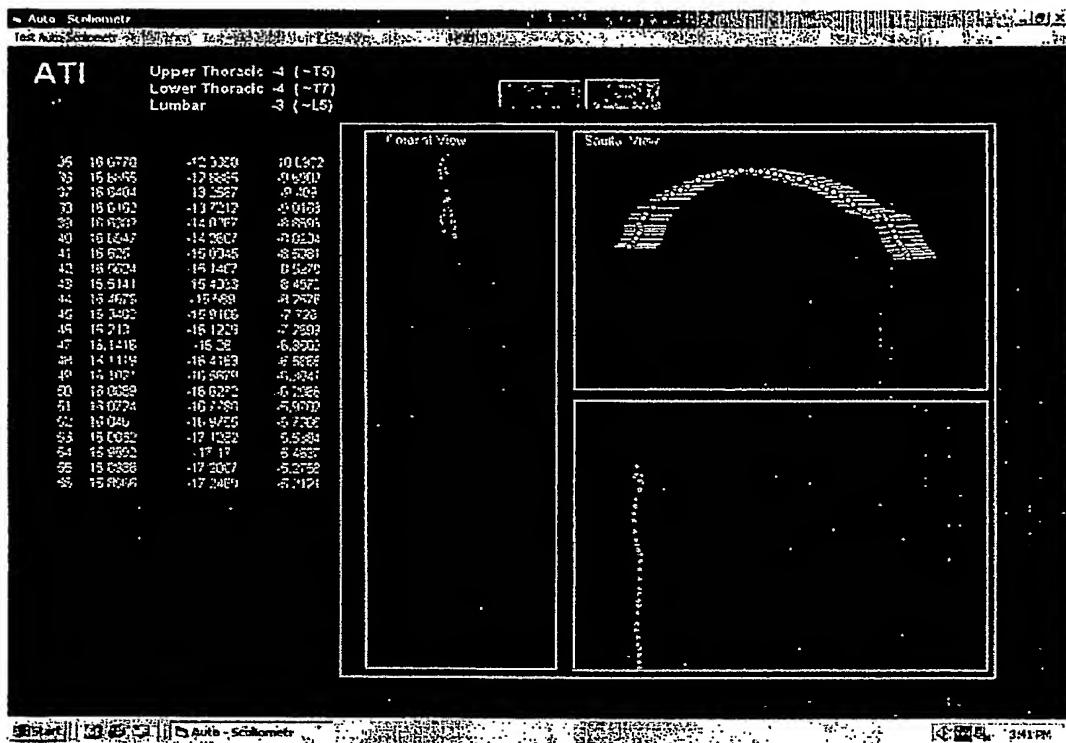


FIG. 4

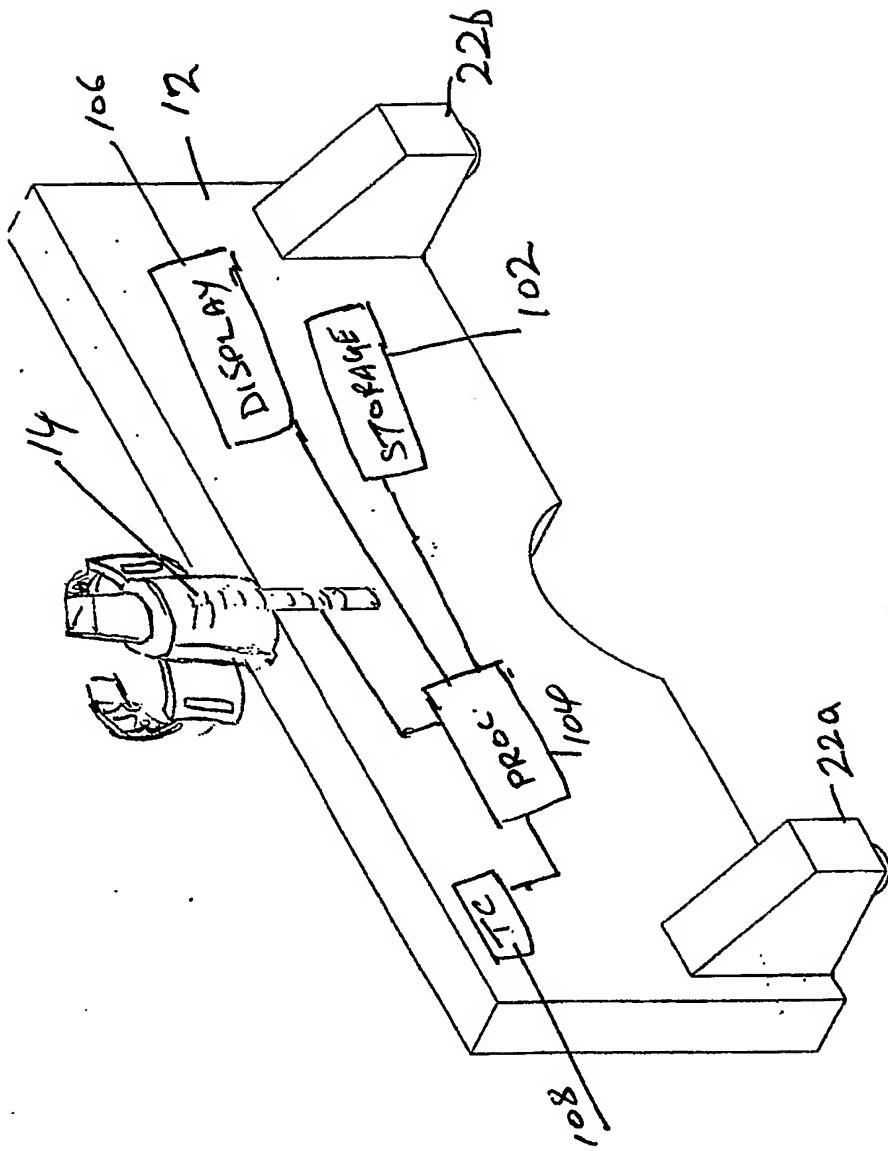


FIG. 5